Job Title:	**Mechanical Design Engineer**	**Location:**	**Ithaca**
Hours:	**Full-time In-person – 40 Hrs/week**	**Rev Date:**	**01-23-25**

Primary Function

The Mechanical Design Engineer is responsible for designing, developing, and testing mechanical components and systems for medical devices including sustaining engineering and new product development. This role requires adherence to ISO, IEC, ANSI, and AAMI standards to ensure compliance with regulatory requirements. The engineer will work closely with cross-functional teams to drive product development from concept to production while ensuring high-quality, safe, durable and effective medical devices.

I. Duties and Responsibilities

Design and Development

- Design and develop mechanical components, assemblies, molds, tooling, and systems for medical devices in compliance with ISO 13485, IEC 60601, and other applicable standards while incorporating feasibility, cost, and maintenance requirements.
- Create 3D CAD models, detailed drawings, and specifications using SolidWorks.
- Conduct tolerance analysis, finite element analysis (FEA), and other engineering calculations to ensure product reliability and performance.
- Develop prototypes, coordinate testing, and validate designs in accordance with regulatory requirements and standards.
- Incorporate design for manufacturability & design for assembly principles into mechanical designs.

Testing and Validation

- Develop test control apparatus and testing procedures to evaluate product performance.
- Participate in verification and validation (V&V) testing, including environmental and mechanical stress testing.
- Support risk assessment, including Failure Mode and Effects Analysis (FMEA), and implement risk mitigation strategies for mechanical designs.
- Provide technical support for troubleshooting, failure analysis, corrective and preventative actions and continuous improvement initiatives.

Collaboration and Integration

- Work closely with electrical, software, and manufacturing engineers to integrate mechanical designs into complete medical device systems and production environment.
- Collaborate with suppliers and manufacturing teams to ensure proper material selection and fabrication processes.
- Work closely with engineering and manufacturing teams to implement design changes, process improvements, and component replacements.

Documentation and Compliance

- Write detailed product requirement specifications and trace matrices.
- Maintain design history files, technical documentation, and engineering change orders in accordance with quality, regulatory, and company standards.
- Specify system components or direct product modifications to ensure conformance with engineering design, performance specifications, and regulatory requirements.
- Oversee production and design work in the machine shop, ensuring compliance with engineering standards.
- Oversee cross functional staff working on design projects, tooling, and manufacturing implementation
- Evaluate mechanical designs of existing products and implement design modifications to enhance manufacturability, efficiency, quality, and performance.
- Perform other work-related duties as assigned by management.

II. Working Relationships

- Reports to the Engineering Director and project managers
- Collaborates with cross-functional teams including Quality Assurance, Regulatory Affairs, Manufacturing, Manufacturing Engineering, and Supply Chain to implement new designs and to resolve existing design issues.
- Works closely with external vendors, contract manufacturers, and testing laboratories.

III. Education and Experience

- Bachelor's Degree in Mechanical Engineering
- 3-5 years' experience is preferred, experience in Medical Device design/standards is a plus

IV. Knowledge, Skills and Abilities

- Strong mechanical design aptitude and practical application of engineering principles in medical device design and production.
- Knowledge of machines and tools, including their designs, uses, repair, and maintenance
- Good understanding of manufacturing processes, raw materials, and cost optimization.
- Proficient in CAD software (SolidWorks) and engineering analysis tools.
- Familiarity with ISO 13485, IEC 60601, and FDA regulations for medical devices is preferred.
- Experience with GD&T, tolerance stack-up analysis, and mechanical testing methodologies.
- Experience in mold design is highly preferred.
- Proficient in Microsoft Office 365's suite of tools.
- Proficiency in technical drawing, blueprint reading, and precision model production

- Ability to analyze operational and user needs to create effective designs that improve system performance and manufacturability
- Ability to identify measures/indicators of system performance and the actions needed to improve or correct design issues
- Excellent verbal & written communication, problem solving, and time management skills
- Self-motivated and organized; experience with project management is a plus.

V. Supervisory Responsibilities

- Directly supervises one Draftsman Engineer, providing mentorship, technical oversight, and performance feedback.

VI. Physical Demands

- Ability to work in an office and laboratory environment.
- Occasional lifting of materials or equipment up to 25 lbs.
- Includes sitting, standing, working at a computer workstation, hands-on work with prototype assembly and testing equipment, and adherence to safety requirements

VII. Work Environment

- Office and laboratory settings with occasional exposure to manufacturing environments.
- Interaction with cleanroom environments may be required
- Occasional travel to suppliers, test labs, or contract manufacturers.

Disclaimer: This Job Description is not intended to be all-inclusive and may be subject to change to include new responsibilities and tasks or change existing ones as management deems necessary to meet the ongoing needs of the company.